DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration
Minneapolis District Office
Central Region
212 Third Avenue South
Minneapolis, MN 55401
Telephone: (612) 334-4100
FAX: (612) 334-4134

March 2, 2004

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 04 – 15

Douglas L. Cook, DDS
Secretary/Treasurer
Per-Tech, Inc.
10971 Clinic Road
Suring, Wisconsin 54174

Dear Dr. Cook:

An inspection of your medical device manufacturing facility was conducted on November 18 and 21, 2003. The inspection revealed that your oral potential meters are adulterated within the meaning of Section 501(h) of the Federal Food, Drug, and Cosmetic Act (the Act), in that the methods used in, or the facilities or controls used for manufacturing, packing, storage, or installation are not in conformance with the Quality System Regulation, Title 21, Code of Federal Regulations (CFR), Part 820.

The deviations are as follows:

1. Failure to establish and maintain procedures for finished device acceptance to ensure that each product run, lot, or batch of finished device meets acceptance criteria [21 CFR 820.80(d)].

2. Failure to document finished device acceptance activities [21 CFR 820.80(e)].

3. Failure to establish and maintain procedures to control the design of the device in order to ensure that specified design requirements are met [21 CFR 820.30(a)].

4. Failure to establish and maintain procedures for receiving, reviewing, and evaluating complaints by a formally designated unit [21 CFR 820.198(a)].

This letter is not intended to be an all-inclusive list of deficiencies at your firm. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and in the Form FDA-483 issued at the conclusion of the inspection may be symptomatic of serious underlying problems in your establishment's quality system. You are responsible for investigating and determining the causes of the violations identified by FDA. You also must promptly initiate permanent corrective and preventive action on your quality system.

Federal agencies are advised of the issuance of all Warning Letters regarding medical devices so that this information may be taken into account when awarding contracts. Additionally, no premarket submissions for Class III devices to which the Quality System/Good Manufacturing Practice deficiencies are reasonably related will be cleared or approved until the deficiencies have been corrected. Also, no Certificates to Foreign Governments will be issued until the violations related to the subject devices have been corrected.

You should take prompt action to correct these violations and to establish procedures whereby such violations do not recur. Failure to do so may result in regulatory action without further notice. These actions include, but are not limited to, seizure, injunction and/or civil penalties.

Please notify this office in writing within 15 working days from the date you receive this letter of the specific steps you have taken to correct the violations. For corrections that you cannot complete within 15 working days, state the reason for the delay and your timeframe for completion. We also ask that you provide documentation of the corrections as they are made and that you explain your plan for preventing these violations in the future.

Please send your reply to Compliance Officer Judy E. Heisick at the address on the letterhead.

Sincerely,

W. Charles Becoat
Director
Minneapolis District

xc: David W. Regiani, DDS
President
Per-Tech, Inc.
10971 Clinic Road
Suring, WI 54174